Walking the Tight Rope: Immunization Law



Thursday, August 1, 2013 2013 N.C. Immunization Conference

Objectives

 To interpret and implement immunization rules and laws.

 To identify appropriate medical and religious exemptions.

To address common immunization law questions.

Online Course

- Accessible in August 2012
 - As of May 28, 2013
 - 219 different people have taken the test
 - Some have taken the test more than once, so over 300 responses have been received
 - Of the 219 people, 157 have passed and received a certificate
 - Of the 157, only 6 received 100% on test portion

Where are N.C. Immunization Laws Found?

- In the General Statutes of North Carolina
 - Chapter 130A Public Health
 - Article 6 Communicable Diseases
 - Part 2 Immunization 130A 152-158

You can access the laws online at www.ncleg.net or through the Immunization Branch website

http://www.immunize.nc.gov/schools/ncruleslaws.htm

State Immunization Law Enforcement

State - Immunization Branch (reports to the CDC regarding:)

- Reporting of Vaccines Administered
- Vaccine Accountability
- Restitution for wasted vaccine

County

- School Principal, Registrar
- Childcare Operator
- Local Health Director



Required Immunizations

According to N.C. laws and rules, every child present in N.C. must be immunized against specific diseases.

diphtheria - hepatitis B

tetanus

- haemophilus influenzae type b

pertussisvaricella

– polio

- rubella

red measles

- mumps

- The schedule for getting the required vaccines is set forth in state regulations
- Parents/guardians are responsible for making sure child is immunized.

Case Facts

 Grandmother presents child for immunization

 Grandmother says child's mother and father asked her to get the child's shots.



Who May Present a Child For Immunization?

- Parent, guardian, person standing in loco parentis
- Any other adult (18 or older) who signs a statement that he/she has been authorized by parent/guardian/person in loco parentis to obtain the immunization
- DSS if it has custody of child
- A minor in some circumstances

When May a Health Care Provider Immunize a Child Presented by Someone Who is Not the Parent?

- Person presenting child for immunization must be an adult (18 years or older).
- Person must sign a statement that he or she has been authorized by the child's parent/guardian to obtain the immunization



Case Facts



- Teenager presents him/herself for immunization - no accompanying adult.
- Immunizations he/she is requesting: HPV and hepatitis B

When Can a Minor Authorize His/Her Own Treatment?

- N.C. Law: A health care provider may accept a minor's consent for "medical health services for the prevention, diagnosis, and treatment of" four conditions:
 - Venereal disease (or sexually transmitted infections)
 - Reportable communicable diseases
 - Pregnancy
 - Abuse of controlled substances
 - Emotional disturbance

May a Minor Consent to Immunizations?

- Most of the immunizations that are required or recommended for children and adolescents prevent either sexually transmitted infections (STI) or communicable diseases that are reportable under N.C. law.
- HPV is not reportable under North Carolina law, but state public health officials consider it a STI. Varicella is the only vaccine that adolescents <u>cannot</u> consent to receive because it is not an STI and it is not reportable.

Can "Any" Minor Give Consent?

- A minor must have
- legal capacity to consent and
- decisional capacity (or competence) that is, the ability to understand health care treatment options and make informed decisions.
- The minor's consent law gives minors legal capacity to consent for immunizations for STIs or reportable communicable diseases, but a health care provider must determine that a minor has the capacity to make the decision on his or her own.

N.C. Law: Exemptions

 Two types of exemptions allowed: Medical and Religious

 No philosophical or personal exemptions are allowed in N.C.



Which Children Qualify for a Medical Exemption?

- Child is exempted when an immunization is medically contraindicated.
- A physician must certify the medical contraindication.
- The contraindication must be recognized by the Advisory Committee on Immunization Practices (ACIP)
- Exceptions can be made by the State Health Director to grant a medical exemption for a non listed contraindication (a licensed N.C. physician must request this)

North Carolina Department of Health and Human Services Women's and Children's Health Section • Immunisation Branch

Medical Exemption Statement

Physician: Please mark the true contraindications/precautions that apply to this patient, then sign and date the back of the form. The signed Medical Exemption Statement verifying true contraindications/precautions is submitted to and accepted by schools, child care programs and other agencies that require proof of immunization. This signed form does not require approval from the State Health Director. For medical exemptions for conditions not listed below, the physician must submit a Physician's Request for Medical Exemption in writing to the State Health Director for approval.

Attach a copy of the most current immunization record.

iame of Patient DOB			
ame of Parent/Guardian			
ddress (patient/parent)			
chool/Child Care			
Medical contrained extinues for immunications are determined by the most recent General Recommendations of the Advisory Committee on Immunization Practices (ACIP), Public Health Services, U.S. Department of Health and Human Services, published in the Centers for Disease Control and Prevention publication, the Morbidity and Mortality Weekly Report.			

A contraindication is a condition in a recipient that increases the risk for a serious adverse reaction. A vaccine will not be administered when a contraindication is present.

A precaution is a condition in a recipient that might increase the risk for a serious adverse reaction or that might compromise the ability of the vaccine to produce immunity. Under normal conditions, vaccinations should be deferred when a precaution is present.

True Contraindications and True Precautions

Vaccine	x	
General for all Vaccines		Contrain dications • Sen ous allergic reaction (i.e., anaphylaxis) after a previous vaccine dose; document vaccine
		Serious allergic reaction (e.g., anaphylaxis) to a vaccine component: document component
		Document type of reaction
		Precautions
		 Moderate or severe acute illness with or without fever
DTaP	000	Contrain dications Severe a literate reaction after a previous dose or to a vaccine component Encephalopathy within seven days after receipt of previous dose of DTP or DTaP Progressive neurologic disorder, including infantile spasms, uncontrolled epi lepsy, progressive encephal-
	0000 0	opathy: defer DTaP until neurologic status clarified and stabilized Precautions Fever greater than 40.5°C (104.9°F) ±48 hours after vaccination of previous dose of DTP or DTaP Hypotonic-hyporesponsive episode ±48 hours after vaccination of previous dose of DTP or DTaP Scizure within 72 hours after vaccination of previous dose of DTP or DTaP Pesistent, inconsolable crying lasting three hours or more ±48 hours after receiving a previous dose of DTP or DTaP Moderate or severe acute illness with or without fever
DT, Td	0 00	Contrain dications • Severe allergic reaction after a previous dose or to a vaccine component Precautions • Guillain-Barré syndrome ± 6 weeks after a previous dose of tetanus toxoi d-containing vaccine • Moderate or severe acute illness with or without fever

DEBTS 3987 (Revised 3/08) Immunization (Raylew 3/10)

Vaccine	x			
EIPV	00 0	Contrain dications • Severe allergic reaction after a previous dose or to a vaccine component Precautions • Pregnancy • Moderate or severe acute i liness with or without fever		
Hepatitis B	000	Contrain dications • Severe allergic reaction after a previous dose or to a vaccine component Precautions • Infart weighing <2,000 grams if mother is documented hepatit is Baurface antigen (HbsAg)-negative at the time of the infart's birth • Moderate or severe a cute illness with or without fever		
НЪ	00 0	Contrain dications Severe allergic reaction after a previous dose or to a vaccine component Age <6 weeks Prec antion Moderate or severe acute i liness with or without fever		
MMR	000 000	Contrain dications • Severe allergic reaction after a previous dose or to a vaccine component • Pregnancy • Known severe immunodeficiency (e.g., hematologic and solid tumors or severely symptomatic human immunodeficiency virus [HIV] infection) Precautions Precautions • History of thrombecytopenia or thrombecytopenic purpum • Moderate or severe a cute i liness with or without fever		
Tdap	000 00 000	Contrain dications • Severe allergy to latex • Severe allergy to latex • Brechalopathy within seven days after receipt of a previous dose of DTP or DTaP Precautions • Guill ian-Barré syndrome ≤6 weeks after a previous dose of tetasus toxoid-containing vaccine • Progressive neurol ogic disorder, including progressive encephalopathy, or uncontrolled epilepsy, urt if the condition has stabilized • Arthus reaction following a previous dose of any vaccine containing tetasus toxoid or diphtheria • Moderate or severe acute illness with or without fever • Pregnancy		
Varicella	000 00	Contrain dications • Severe allergic reaction after a previous dose or to a vaccine component • Substantial suppression of cellular immunity • Pregnancy • Pregnancy • Recent (al I months) receipt of antibody-containing blood product (specific interval depends on product) • Moderate or severe a cute i liness with or without fever		
Attach m		Instructions Instructions Purpose: To provide physicians with a mechanism to document inc.		

N.C. Physician's Name (please print) Address Phone N.C. Physician's Signature/Date

DIRES 3987 (Revised 3/08) Immunization (Raview 3/10)

LINEST UCT LODGE	
Purpose:	To provide physicians with a mechanism to document true medical exemptions.
Personation	1. Complete national information (name, DOB, sklows

- and school/child care). 2. Check applicable vaccine(s) and exemption(s).
- 3. Complete date exemption ends and physic is n
- 4. Attach a copy of the most current immunization record.
- 5. Retain copy for file.

6. Return original to person requesting for m. Reorder Immunication Branch

1917 Mail Service Center Raleigh, NC 27699-1917 Phone 1-877-873-6247

For questions call (919) 707-5550

North Carolina Department of Health and Human Services Women's and Children's Health Section

PHYSICIAN'S REQUEST FOR MEDICAL EXEMPTION

Instructions: Use this form to request an exemption for an immunization not specified in North Carolina Administrative Code (10 NCAC 41A. 0404) as a valid contraindication to immunizations. Also, attach a copy of the most current immunization record

Name of Patient	DOB
Name of Parent/Guardian	
Address (patient)	
(parent)	
School/Child Care	
zations required by G.S. 130A-152. If a physician licensed t be detrimental to a person's health due to the presence of on receive the specified immunization as long as the contraind	Health Services shall adopt by rule a list of medical contraindications to immuni- to practice medicine in this State certifies that a required immunization is or may se of the contraindications listed by the Commission, the person is not required to lication persists. The State Health Director may, upon request by a physician li- emption to a required immunization for a contraindication not on the list adopted
Attach Most Cu	urrent Immunization Record.
N.C. Physician's Name (Please print)	Send completed form to:
N.C. Physician's Signature/Date Address	State Health Director Department of Health and Human Services Immunization Branch 1917 Mail Service Center Raleigh, NC 27699-1917
Telephone Number	
DHHS 3995 (Revised 4/06)	

Immunization (Review 4/09)

INSTRUCTIONS

Purpose: To provide physicians with a mechanism to request a medical exemption from the State Health

Director.

Preparation: 1. Complete the Request for Exemption (including physician name, signature and date, address and

telephone number).

2. Retain copy for file.

3. Copy to person requesting exemption.

4. Attach most current immunization record.

5. Send request to:

Department of Health and Human Services

Immunization Branch 1917 Mail Service Center Raleigh, NC 27699-1917

Reorder: Immunization Branch

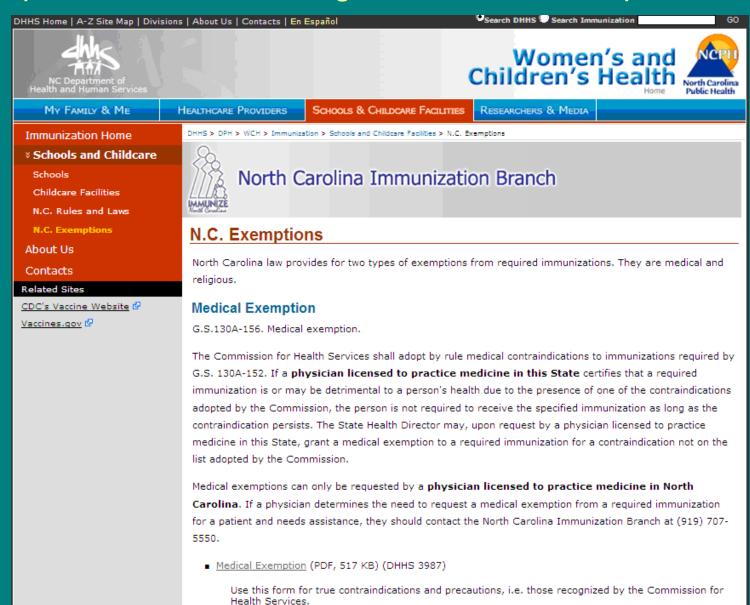
NCDHHS

1917 Mail Service Center Raleigh, NC 27699-1917

1-877-873-6247

DHHS 3995 (Revised 4/06) Immunization (Review 4/09)

http://www.immunize.nc.gov/schools/ncexemptions.htm



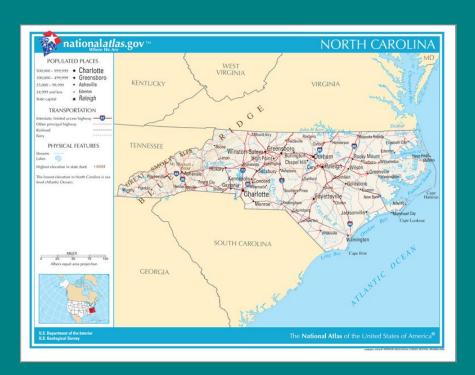
Use this form for contraindications and precautions not recognized as valid.

Physician's Request for Medical Exemption (PDF, 41 KB) (DHHS 3995)

- Once a medical exemption that needs approved by the State Health Director has been reviewed:
 - The original signed letter stating approval or denial of exemption is sent to the physician who requested the exemption.
 - A copy of the letter with the decision is sent to the parent or patient if age 18 or older.
 - It is the responsibility of the parent or adult to provide a copy of the exemption to the school/childcare/or college
 - The Regional Immunization Consultant in the facilities area will notify the school/childcare/or college if the exemption has been approved or denied, but does not provide a copy of the notification.

 It is possible that the 30 day grace period to enter a childcare, school, or college will end prior to the student receiving a response to a Physician's Request for Medical Exemption. In that case, the student can remain in childcare, school, or college, as usual, until a decision is reached.

Case Facts



 A childcare located in N.C. borders the state of Virginia and a child enrolls with a medical exemption signed by a Virginia physician.

Is this exemption valid?

Valid Medical Exemptions

- To have a valid Medical Exemption in N.C., it must be signed by a N.C. licensed physician (some physicians located near neighboring states are licensed in more than one state).
- This also applies for a college student with a medical exemption from another state. They must get a medical exemption from a N.C. licensed physician.

Which Children Qualify for a Religious Exemption (RE)?

- Child is exempted when the bona fide religious beliefs of the child's parent or guardian are contrary to the immunization requirements.
- Parent claims exemption by writing a statement of religious objection for each child for whom exemption is claimed.
- There is no required "Form"
- Special Religious Exemption for hep B, MMR, and Varicella
 - A religious exemption can be accepted for only hep B, MMR, or Varicella or just for all three of those vaccines. This is based on how the vaccines are made and that hepatitis B can be transmitted sexually.

Common Questions About Religious Exemptions (RE)

- Does a religious exemption need to be signed annually?
 - No
- Should a student entering college with a religious exemption sign the exemption or should the parents?
 - Anyone 18 or over should sign their own religious exemption
- If a child that has a RE wants to transfer to a different provider office, does the new provider have to accept them?
 - No, some provider offices do not see children with RE's or delayed immunization schedules.

Does N.C. Recognize a Philosophical Objection to Immunization?

- Common philosophical or personal objections:
 - Concern that risk of immunization outweighs benefits
 - Different views of science of immunization
 - Don't agree with governmental mandate
- No. philosophical or personal exemptions are not accepted in N.C.

N.C. Law: Immunizations & Schools

 If a child is unimmunized and not eligible for a medical or religious exemption, the child may be excluded from school or childcare.



N.C. Law: Requirements for Childcare or School Entry

- Parent/guardian must present a certificate of immunization or documentation of exemption.
- If certificate is not presented or incomplete, school principal or childcare operator must give parent notice of deficiency.
- Parent has 30 <u>calendar</u> days to obtain immunization(s) or child is excluded from childcare or school until he/she meets requirements.

What is Required for a Certificate of Immunization?

- Name of child
- Name of child's parent or guardian
- Address of the child
- Child's date of birth
- Child's gender

- Number of doses of the vaccine given
- Date the doses were given
- Name and address of the physician or local health department administering the vaccine

Acceptable Certificates of Immunization for School Entry

- What does a student need that is transferring from one K-12 school to another K-12 school within N.C.?
 - A student needs an official certificate of immunization with all of the information that is required from the previous slide. If a student's transcript includes a shot record with all of the required information it is acceptable.

- What does a student need that is transferring into a N.C. K-12 school from another state?
 - A student needs an official certificate of immunization with the student's name, address, date of birth, gender; the type and number of doses of administered vaccine; the dates of the first MMR and the last DTP and polio; and the name and address of the physician administering the required immunizations.

What Type of Immunization Record Does a Student Need to Enter College?

 Someone entering college (public, private, or religious) must have a certificate of immunization or a record of immunization from a high school located in N.C. indicating the immunizations the person has received. For students entering college from another state, they must have all of the required information stated in previous slide regarding an official certificate of immunization.



N.C. Law: Isolation/Quarantine

 If there is an outbreak of a vaccinepreventable disease, unimmunized children may need to be isolated or quarantined during the outbreak.

 This applies to children who have a valid exemption from the immunization(s) requirements, as well as non-exempt unimmunized children.

N.C. Law: Enforcement of Immunization Requirements

- In theory, immunization requirements could be enforced the same as any other public health law (charge with misdemeanor, obtain court order).
- In practice, the issue of compliance with immunization requirements usually is addressed when a child enters childcare, school, or college.



Why are Schools, Childcare Centers, and Colleges Required to Keep an Immunization Record for Each Attendee?

 Schools, childcare centers, and colleges are required by law to have an immunization record on file for each attendee. This information is useful if there is a vaccine-preventable disease outbreak. It is also important to know what attendees have exemptions to vaccines in case people need excluded if there is a disease outbreak.

Common Vaccine Questions

- What are the hepatitis B requirements?
 - Three doses; one dose by age three months, a second dose before age five months and a third dose by age 19 months. However:
 - (A) The last dose of the hepatitis B vaccine series shall not be administered prior to 24 weeks of age;
 - (B) Individuals born before July 1, 1994 are not required to be vaccinated against hepatitis B.

- What are the Varicella requirements?
 - Any child born on or after April 1, 2001 is required to have 1 dose of Varicella on or after their 1st birthday
 - If a child has proof of immunity from Varicella;
 they do not need a dose of vaccine. The following meets the proof of immunity requirements:
 - Lab report, Doctor states child had disease, or parent states that child had disease

- Why do some colleges with nursing (or other medical) programs not accept the verbal report of having varicella disease from an incoming student?
 - Schools/colleges/childcares can require more than the law but must at least meet the requirements in the law. College students entering a medical program may be required to provide proof of immunity to varicella through a lab report or physician report.

- What are the Polio Requirements
 - 2 doses by age 5 months
 - 3rd dose by 19 months of age
 - Booster dose before enrolling in school for the first time
- If the third dose is administered on or after the 4th birthday - the 4th dose is not required

In what situation does the 4 day rule apply?

(These are just a few examples)

- DTaP: A child needs a dose on or after their 4th birthday;
 the dose is valid if given 4 days before the 4th birthday
- MMR & Varicella: A child needs a dose on or after their 1st birthday; the dose is valid if given 4 days before the 1st birthday
- Hepatitis B: 24 weeks of age is required before the last dose of hepatitis B is given, but 4 day rule applies, if 4 days before the 24 week birth date the dose is valid
- Hepatitis A: The recommended and minimum interval between the 1st and 2nd dose is 6 calendar months—if the 2nd dose is administered 4 days or less prior to the minimum interval the dose is valid.

The 4 Day Rule continued.....

 Vaccine doses administered up to 4 days before the minimum interval or age can be counted as valid. This 4-day recommendation does not apply to rabies vaccine because of the unique schedule for this vaccine. Doses administered 5 days or earlier than the minimum interval or age should not be counted as valid doses and should be repeated as age appropriate. The repeat dose should generally be spaced after the invalid dose by an interval at least equal to the recommended minimum interval..... This is from the May 2012, 12th Edition Epidemiology and Prevention of Vaccine preventable Diseases. Chapter 2, page 14

The 4 Day Rule continued.....

NC Immunization Law enforces the minimum age portion of this

10A NCAC 41A .0401 DOSAGE AND AGE REQUIREMENTS FOR IMMUNIZATION

– b) The healthcare provider shall administer immunizations in accordance with this Rule. However, if a healthcare provider administers vaccine up to and including the fourth day prior to the required minimum age, the individual dose is not required to be repeated. Doses administered more than 4 days prior to the requirements are considered invalid doses and shall be repeated.

- What routine titers from lab results showing immunity are acceptable for school entry?
 - MMR and Varicella
- A request for a medical exemption from hepatitis B vaccine must be submitted to the State Health Director for review and approval. This is not routinely done; only for special circumstances. The titer lab results must be submitted with the exemption.

- Is a signature from a parent/guardian required by law when a child is immunized?
 - No, a signature is not required, but a provider can go beyond and get a signature or acquire a "blanket signature".
 - A blanket signature: a provider office creates a form that a parent/guardian signs that will grant permission for all vaccines the child will get over the years.
- There is a form on NCIR that can be used, the New Client Form

What Does "in process" Mean?

- If the administration of vaccine in a series of doses given at medically approved intervals requires an excess of 30 calendar days, the student/child shall be allowed to attend school upon written certification by a physician to obtain the required immunization and considered "in process".
- An example of "in process":
 - A student entering kindergarten is missing both required doses of MMR vaccine. The student must receive the first dose during the 30 day grace period to remain in school. Even though the student has not received the second dose within the 30 day grace period, they may attend school and be considered "in process" as long as they get the second dose when it is medically appropriate. A student having an appointment to receive a vaccine after the 30 day grace period is over, is not considered "in process."

Access to Immunization Records

- Who is allowed access to Immunization information?
 - State and Local health departments
 - Patient's physician
 - Schools K-12, public and private
 - Licensed childcare facilities
 - Colleges and universities, public and private
 - Health Maintenance Organizations
 - State and Local health departments outside N.C.

Case Facts

 Parent has a pastdue account with a health care provider (HCP).

 HCP refuses to provide an immunization record until account is paid





Can HCP Refuse to Provide an Immunization Record Because Account is Unpaid?

- No. A parent has the right under HIPAA to review and obtain a copy of child's information - an unpaid account is not grounds for denying this right.
- Other entities have a right under state law to demand immunization information from HCPs, including: health departments, schools, and childcares.

Who Do I Contact for Help Interpreting Immunization Laws?

- Regional Immunization Consultants (www.immunize.nc.gov/contacts.htm)
- Immunization Branch –
 Central Office: 919-707-5550
- Your Local Health Director
- Your Local County Attorney

Commonly missed questions

Routine titers for varicella and pertussis showing immunity are acceptable for school entry.

29% of responders missed this question. Routine titers are ONLYacceptable for: Measles, Mumps, Rubella, Varicella

A parental signature is required when a child is receiving vaccinations.

23% of responders missed this question. As mentioned earlier, a signature is <u>NOT</u> required.

The N.C. Immunization Branch can create or change immunization laws at anytime.

23% of responders missed this question. Creating or changing laws is a complex and lengthy process.

- It is the 30th day after the first day of school and a parent hands you an appointment card for her son to get his 2nd MMR two weeks from today...
- A) The student can remain in school and is considered "in process"
- B) The student must be excluded from school for the next 2 weeks
- C) Suggest the parent go to the health department or somewhere else to get vaccine, but will be excluded until gets the dose
- D) Suggest the parent submit a religious exemption for MMR

47% of responders choose the "in process" answer, only 45% chose the correct answer (C)

Two new students are entering 3rd grade. One student is transferring from another school in N.C., while the other student is from NY. Both students have the same requirements as far as what is acceptable as a shot record for school entry.

77% of responders miss this question. The information that differs for an out of state student is: the dates of the first MMR and the last DTP and polio are the only required dates necessary. They still need to include the number of doses received of each required vaccine. In state students require a more detailed shot record with all dates required.

The 30 day grace period for getting vaccinations for school has ended. A student has applied for a medical exemption but has not received a decision yet. The student...

- A) Must stay home until a decision is made about the exemption
- B) Can remain in school but will be separated from other students
- C) Can remain in school, as usual, until a decision is made
- Must stay home and the school will send a tutor to the home

57% of responders missed this question. While a medical exemption is waiting for an official response, a child can remain in school or childcare as usual (C is correct).

If interested in the online law module, or other Immunization Branch courses: http://www.immunize.nc.gov/providers/ncip education.htm

Questions????